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10/553,830	07/03/2006	Yoshikazu Morita	8062-1032	6299
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EXAMINER				
KIM, TAEYOUN				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,830

Applicant(s)

MORITA ET AL.

Examiner

Taeyoon Kim

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 1/15/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-17 are pending.

Response to Amendment

Applicant's amendment and response filed on 1/15/2009 has been received and entered into the case.

Claims 6-17 are newly added, and claims 1-17 are pending.

Newly submitted claims 11-16 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 11-16 are drawn to a method whereas the originally presented claims 1-5 are drawn to a product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-16 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-10 and 17 have been considered on the merits. All arguments have been fully considered.

Response to Arguments

In the response to the previous office action, applicant amended the claims to disclose intended effects or results of the skin collagen production promoter upon application to the skin. Applicant alleged that the cited references do not teach such effects obtainable from the claimed product. This argument has been fully considered but found not persuasive.

M.P.E.P. § 2112.01 recites, "Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." See *In re Spada* (citations omitted).

Since the product of the cited references is considered substantially similar, if not identical, it is an inherent property of the product to possess the same effect(s) from the intended use.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

M.P.E.P. §2111.02 states, "Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071

(Fed. Cir. 1987). (The claim at issue was directed to a driver for setting a joint of a threaded collar*>;< however>,< the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework - the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." Id. at 1073, 828 F.2d at 754.).

Therefore, the cited references anticipate the subject matter of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Takada et al. (EP 1010430A1; IDS ref.).

Claim 1 is interpreted as a skin collagen production promoter comprising a milk-derived basic protein fraction as an active ingredient.

Takada et al. teach a milk-derived basic protein fraction for periodontal

application such as mouthwash (cosmetic), food or drink (par. 9) and the fraction contains more than 15% by weight of basic amino acids (par. 8), and the molecular weight distribution is 3,000 to 80,000 Daltons by SDS-PAGE (par. 8).

Takada et al. also teach a limitation drawn to a process step disclosed in claim 3 to obtain milk-derived basic protein fraction using a cation exchange resin and eluting with a salt concentration of 0.1 to 1 M (par. 11).

Takada et al. teach the milk-derived basic protein fraction can be in amount of 0.1, 0.5 or 1 weight percent in food, drink or cosmetic (mouthwash) (see Tables 2-4), and thus meet the limitation of claims 6-8.

With regard to the limitation drawn to the milk-derived basic protein fraction being at least 95% by weight proteins, the reference does not particularly disclose the limitation. However, Takada et al. teach that the milk-derived basic protein is purified with cation-exchange resin, which is the same method disclosed in the specification of the current invention (p.5, 9-10 and 12; Example 2), it is the examiner's position that the product of Takada et al. has substantially similar, if not identical, weight percentage of milk-derived basic protein as claimed.

Although Takada et al. do not particularly teach that the milk-derived basic protein composition is a skin collagen production promoter, the product of Takada et al. is expected to have the same properties as the claimed invention and thus it is expected that the product of Takada et al. has the same effect on skin collagen production as the claimed invention.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth

all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "skin collagen production" does not affect the patentability of the claimed composition. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application.

M.P.E.P. § 2112.01 recites, "Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." See *In re Spada* (citations omitted).

M.P.E.P. §2112 also states that "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the

same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

With regard to the newly introduced limitation drawn to intended results of promoting skin collagen production and improving skin wrinkling, sagging, dryness feeling or chapping when orally administered or topically applied to the skin in the claims, the limitations in the "wherein" clause are merely states the result of the limitations in the claim and therefore, adds nothing to the patentability or substance of the claim. Therefore, this phrase does not limit the claim. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 USPQ2d 1747 (Fed. Cir. 2001).

Since the product of the cited references is considered substantially similar, if not identical, it is an inherent property of the product to possess the same effect(s) from the intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Thus, the reference anticipates the claimed subject matter.

Claims 1-9 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Takada et al. (US 5,976,597; IDS ref.).

Takada et al. teach a basic protein and/or a basic peptide composition derived from milk (milk-derived basic protein or peptide) by protease degradation (abstract, col. 1, lines 6-15).

Takada et al. teach the amino acid composition comprising 17.8% of basic amino acid (col. 4, lines 46-47), thus meet the limitation of 15% by weight or more in claim 2.

Takada et al. teach the same process steps of protease degradation (claim 1) and steps of isolating a fraction derived from milk basic protein including an absorption with a cation exchange resin, and elution with an eluent having a salt concentration of 0.1 to 1 M (col. 2, lines 55-62).

Takada et al. teach the range of molecular weight of the basic protein composition being 3,000-24,000 Dalton (Example 2), and thus meet the limitation of claim 9.

With regard to the limitation drawn to the milk-derived basic protein fraction being at least 95% by weight proteins, the reference does not particularly disclose the limitation. However, Takada et al. teach that the milk-derived basic protein is purified with cation-exchange resin, which is the same method disclosed in the specification of the current invention (p.5, 9-10 and 12; Example 2), it is the examiner's position that the product of Takada et al. has substantially similar, if not identical, weight percentage of milk-derived basic protein as claimed.

Takada et al. teach that the milk-derived basic protein or basic peptide fraction composition can be taken orally and useful as a supplement to food or drink, therefore, this teaching anticipates the food or beverage product as in claim 4.

Although Takada et al. do not teach that the milk-derived basic protein or basic peptide fraction composition is a skin collagen production promoter or a cosmetic, the product of Takada et al. is expected to have the same properties as the claimed invention and thus the product of Takada et al. is expected to have the same effect on skin collagen production as the claimed invention.

Although Takada et al. do not particularly teach the composition is being used as a cosmetic (intended use) as claimed in claim 5, the purpose of the composition without any distinct physical, chemical and structural properties does not limit the claimed product.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "skin collagen promoter" or "a cosmetic for promoting skin collagen production" does not affect the patentability of the claimed composition. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application.

M.P.E.P. § 2112.01 recites, "Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." See *In re Spada* (citations omitted).

M.P.E.P. §2112 also states that "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

With regard to the newly introduced limitation drawn to intended results of promoting skin collagen production and improving skin wrinkling, sagging, dryness feeling or chapping when orally administered or topically applied to the skin in the claims, the limitations in the "wherein" clause are merely states the result of the limitations in the claim and therefore, adds nothing to the patentability or substance of the claim. Therefore, this phrase does not limit the claim. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 USPQ2d 1747 (Fed. Cir. 2001).

Since the product of the cited references is considered substantially similar, if not identical, it is an inherent property of the product to possess the same effect(s) from the intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada et al. ('597).

Takada et al. anticipate the subject matter of claims 1-9 and 17, and thus render them obvious (see above).

With regard to the limitation of the molecular weight distribution of 500 to 4,000 daltons of milk-derived basic peptide fraction of claim 10, Takada et al. teach that the milk-derived basic peptide composition has a molecular weight distribution ranging less than 9,000 or 10,000 daltons (Examples 5 and 6), which overlaps the claimed range of 500 to 4,000 daltons.

M.P.E.P. §2144.05 states that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered *prima facie* obvious in view of prior art reference teaching

that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms]." The court stated that "by stating that 'suitable protection' is provided if the protective layer is 'about' 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range."). Similarly, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.).

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Taeyoon Kim
AU-1651